

## ATRICURE CRYO MODULE SYSTEM 510(K) SUMMARY

### GENERAL INFORMATION

<b>Trade Name</b>	AtriCure Cryo Module System (ACM, Cryo1 and cryoICE)
<b>Manufacturer</b>	AtriCure, Inc 6217 Centre Park Drive West Chester, OH 45069
<b>Contact</b>	James L. Lucky VP of Quality Assurance and Regulatory Affairs (513) 755-5754
<b>Establishment Registration Number</b>	3003502395
<b>Predicate Device</b>	AtriCure Cryo Module System (ACM, Cryo1 and cryoICE) [K111042]
<b>Date Compiled</b>	June 24, 2011
<b>Classification</b>	Class II
<b>Regulation</b>	21 CFR 878.4350
<b>Product Code</b>	GEH

### INDICATIONS FOR USE

The AtriCure Cryo Module System is intended for use in the cryosurgical treatment of cardiac arrhythmias. The System consists of the AtriCure Cryo Module (ACM)—a non-sterile, reusable device—used with the Cryo1 cryo-ablation probe—a sterile, single use device—and/or the cryoICE cryo-ablation probe—a sterile, single use device.

### DEVICE DESCRIPTION

The AtriCure Cryo Module (ACM) unit is a non-sterile reusable electro-mechanical and pneumatic cryogenic surgical system that delivers a cryogenic energy source, namely Nitrous Oxide, to an AtriCure cryo-ablation probe to create lines of ablation through cardiac tissue for the treatment of cardiac arrhythmias. The AtriCure cryo-ablation probe (Cryo1 or cryoICE) is a sterile, single use, cryosurgical device to be used in conjunction with the AtriCure Cryo Module or frigitronics CCS-200 Cardiac Cryosurgical System [K811390] to freeze target tissue, blocking the electrical conduction pathways by creating an inflammatory response or cryonecrosis.

## **MATERIALS**

All materials used in the manufacture of the AtriCure Cryo Module System are safe and suitable for their intended use and suitable for their use with pressurized nitrous oxide. The ACM is not intended for patient contact. Testing has been previously conducted in accordance with ISO 10993-1 to ensure biocompatibility of all appropriate materials in the AtriCure cryo-ablation probes (Cryo1 and cryoICE).

## **TESTING**

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices. Bench comparison testing, transit testing, electrical safety, electromagnetic compatibility, design verification and validation, software validation, etc. were completed to show that the ACM is substantially equivalent and in conformance international standards and device specifications. The standards and FDA Guidance used to determine substantial equivalence include, but are not limited to:

- UL 60601-1: Medical Electrical Equipment, Part 1: General Requirements for Safety. (2006)
- EN 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Safety (1998) +A1 +A2, 2nd Edition
- IEC 60601-1-2: Collateral Standard- Electromagnetic Compatibility – Req. & Tests (2007)
- EN 55011: Industrial, scientific and medical (ISM) radio-frequency Equipment. Electromagnetic disturbance characteristics. Limits and methods of measurement. (2007)
- ISTA Procedure 3A: Packaged – Product for Parcel Delivery System Shipment 70kg (150 lb) or Less; (2008)
- ASTM F882-84: Standard Performance and Safety Specification for Cryosurgical Medical Instrument's (2002)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Issued May 11, 2005)

## **SUMMARY OF SUBSTANTIAL EQUIVALENCE**

The AtriCure Cryo Module System is equivalent to the predicate products. The intended use, method of operation, methods of construction and materials used, are substantially equivalent to existing legally marketed predicate products.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

AtriCure, Inc.  
c/o Mr. Mark Job  
Reviewer  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
Buffalo, MN 53313

AUG - 3 2011

Re: K112072  
Trade/Device Name: AtriCure Cryo Module System (ACM, Cryo1 and cryoICE)  
Regulatory Number: 21 CFR 878.4350  
Regulation Name: Cryosurgical Unit and Accessories  
Regulatory Class: II (two)  
Product Code: GEH  
Dated: July 19, 2011  
Received: July 20, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

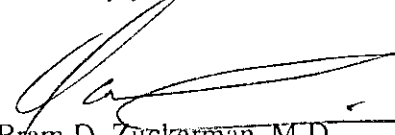
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
for Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): 12112072

Device Name: AtriCure Cryo Module System (ACM, Cryo1 and cryoICE)

Indications for Use:

The AtriCure Cryo Module System is intended for use in the cryosurgical treatment of cardiac arrhythmias. The System consists of the AtriCure Cryo Module (ACM)—a non-sterile, reusable device—used with the Cryo1 cryo-ablation probe—a sterile, single use device—and/or the cryoICE cryo-ablation probe—a sterile, single use device.

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDPH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number 12112072